2	§ 100070. SCRO Committee Review and Notification.
3	(a) CIRM-funded research involving the procurement or use of human oocytes may not
4	commence without SCRO committee review and approval in writing. For such SCRO
5	committee review and approval, a member of the committee with expertise in assisted
6	reproduction shall be present. The designated SCRO committee may require that modification be
7	made to proposed research or documentation of compliance with the requirements of subdivision
8	(a)(3) of this regulation as a condition of granting its approval. At a minimum, the SCRO
9	committee shall require the investigator to:
10	(1) Provide an acceptable scientific rationale for the need to use oocytes
11	including a justification for the number needed. If SCNT is proposed a justification for
12	SCNT shall be provided.
13	(2) Demonstrate experience, expertise or training in derivation or culture of
14	human or nonhuman stem cell lines.
15	(3) Provide documentation of compliance with any required review of the
16	proposed research by an IRB, Institutional Animal Care and Use Committee (IACUC),
17	Institutional Bioethics Committee (IBC), or other mandated review.
18	(b) CIRM-funded research involving use of human embryos may not commence without
19	SCRO committee review and approval in writing. The designated SCRO committee may
20	require that modification be made to proposed research or documentation of compliance with the
21	requirements of subdivision (b)(3) of this regulation as a condition of granting its approval. At a
22	minimum, the SCRO committee shall require the investigator to:

1

100070.OAL.Revised

Adopt 17 Cal. Code of Regs. section 100070 to read:

10/03/06

1	(1) Provide an acceptable scientific rationale for the need to use em	<u>bryos</u>	
2	including a justification for the number needed.		
3	(2) Demonstrate experience, expertise or training in derivation or cu	ılture of	
4	human or nonhuman stem cell lines.		
5	(3) Provide documentation of compliance with any required review	of the	
6	proposed research by an IRB, Institutional Animal Care and Use Committee	e (IACUC),	
7	Institutional Bioethics Committee (IBC), or other mandated review.		
8	(c) CIRM-funded research with the aim to derive or create a covered stem	cell line may	
9	not commence without SCRO committee review and approval in writing. The desi	gnated SCRO	
10	committee may require that modification be made to proposed research or document	ntation of	
11	compliance with the requirements of subdivision (c)(4) of this regulation as a condi-	tion of	
12	granting its approval. At a minimum, the SCRO committee shall require the investigator to:		
13	(1) Provide an acceptable scientific rationale for the need to derive	a covered	
14	stem cell line.		
15	(2) If SCNT is proposed as a route to generating human stem cell lin	es, a	
16	justification for SCNT shall be provided.		
17	(3) Demonstrate experience, expertise or training in derivation or cu	ılture of	
18	human or nonhuman stem cell lines.		
19	(4) Provide documentation of compliance with any required review	of the	
20	proposed research by an IRB, Institutional Bioethics Committee (IBC), or o	ther_	
21	mandated review.		
22	(5) Document how stem cell lines will be characterized, validated, stored, a	and distributed	
	10/03/06 2 100070.OAL.R	evised	

1	to ensure that the confidentiality of the donor(s) is protected.			
2	(d) CIRM-fun	ded purely in vitro research utilizing cov	vered stem cell lines may not	
3	commence without w	ritten notification to the designated SCR	O committee. At a minimum, the	
4	notification shall:			
5	(1) Pro	ovide assurance that all covered stem ce	ell lines have been acceptably	
6	derived.			
7	<u>(2)</u> Pro	ovide documentation of compliance with	h any required review of the	
8	proposed resea	arch by an IRB, IACUC, IBC, or other r	mandated review.	
9	(e) CIRM-fur	nded research introducing covered stem	cell lines into non-human animals	
10	or introducing neural-	-progenitor cells into the brain of non-hu	uman animals at any state of	
11	embryonic, fetal, or postnatal development may not commence without SCRO committee review			
12	and approval in writing. The designated SCRO committee may require that modification be			
13	made to proposed research or documentation of compliance with the requirements of subdivision			
14	(e)(3) of this regulation as a condition of granting its approval. The SCRO committee may			
15	establish guidelines and procedures for expedited review of animal research so that review by the			
16	entire SCRO committe	tee is not required. At a minimum, the So	CRO committee shall require the	
17	investigator to:			
18	<u>(1) Pro</u>	ovide an acceptable scientific rationale f	for introducing stem cells into non-	
19	<u>human animal</u>	<u>ls.</u>		
20	(2) Pro	ovide assurance that all covered stem ce	ell lines have been acceptably	
21	derived.			
22	(3) Ev	valuate the probable pattern and effects of	of differentiation and integration of	
	10/03/06	3	100070.OAL.Revised	

1	the human cells into the nonhuman animal tissues.
2	(4) Provide documentation of compliance with any required review of the
3	proposed research by an IRB, IACUC, IBC, or other mandated review.
4	(f) CIRM-funded research introducing stem cells from covered stem cell lines into a live
5	born human may not commence without SCRO committee review and approval in writing. The
6	designated SCRO committee may require that modification be made to proposed research or
7	documentation of compliance with the requirements of subdivision (f)(4) of this regulation as a
8	condition of granting its approval. At a minimum, the SCRO committee shall require the
9	investigator to:
10	(1) Provide an acceptable scientific for rationale introducing stem cells into
11	<u>humans.</u>
12	(2) Provide assurance that all covered stem cell lines have been acceptably
13	derived.
14	(3) Evaluate the probable pattern and effects of differentiation and integration of
15	the human cells into the human tissues.
16	(4) Provide documentation of compliance with any required review of the
17	proposed research by an IRB, IACUC, IBC, or other mandated review.
18	(g) In cases where SCRO committee approval is required, a SCRO committee shall
19	notify investigators in writing of its decision to approve or disapprove the proposed research
20	activity, or of modifications required to secure SCRO committee approval of the research
21	activity. If the SCRO committee decides to disapprove a research activity, it shall include in its
22	written notification a statement of the reasons for its decision and give the investigator an
	10/03/06 4 100070.OAL.Revised

- 1 opportunity to respond in person or in writing.
- 2 (h) SCRO committee approvals shall be reviewed no less frequently than once per year.
- 3 The renewal review shall confirm compliance with all applicable rules and regulations. The
- 4 SCRO committee may establish guidelines and procedures for expedited review of renewals so
- 5 that review by the entire SCRO committee is not required.
- 6 Note: Authority cited: Article XXXV, California Constitution; Section 125290.40(j), Health and

Safety Code. Reference: Sections 125290.40, 125290.55, Health and Safety Code.

Deleted: 4

7